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10/643,554	08/18/2003	Jeffrey J. Thramann	46620.830007.US1	4937

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EXAMINER
TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,554	THRAMANN, JEFFREY J.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 02 August 2006. Any objections or rejections not addressed in this Office Action are considered to be withdrawn.

Specification

1. Examiner accepts the corrections made to the abstract and disclosure.

Claim Objections

2. Claim 19 is objected to because of the following informalities: Incorrect grammar. Replace the term "extended" with --extend--. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 10, and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claim 1, the claimed subject matter "a puncture point on a wall of the vessel" constitutes part of the human body, which does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). Alternate language such as "adapted to be" should be used. For example, the sentence could be re-written to read --the main vessel stent graft having an access port on a wall adapted to be aligned with a puncture point on a wall of the vessel--.

Regarding claim 10, the claimed subject matter "branch vessels" constitutes part of the human body, which does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). Alternate language such as "adapted to be" should be used. For example, the sentence could be re-written to read --including at least one access port on a wall adapted to be aligned with a corresponding number of branch vessel--. The same applies to the portion of the claim where the term "will" has been removed.

Regarding claim 16, the claimed subject matter "main vessel" constitutes part of the human body, which does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). Alternate language such as "adapted to" should be used. For example, the sentence could be re-written to read --a main vessel stent graft adapted to reside in a main vessel--.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,3, 6, and 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al. (Patent No. 5,709,713).

Regarding claim 1, Evans et al. disclose a main vessel stent graft (Figure 16, element 52) inherently capable of extending in a vessel until it is proximate a portion of a vascular anatomy to be bypassed. Figure 15 shows an access port (55) on the main vessel stent graft (52) that is inherently capable of being aligned with a puncture point on a wall of a vessel, since all one would have to do is rotate and/or move the stent graft (52) in a particular direction until the port is aligned with the puncture point. Evans et al. further disclose a bypass stent graft (56) comprising a proximate end (not labeled) and a distal end (not labeled). Figure 16 shows the proximate end of the bypass stent graft (56) is received in the access port (55) on the wall of the main vessel stent graft (52) in a sealing relationship. The bypass stent graft (56) is flexible (column 2, lines 12-15) and although it is "usually" shorter, it could be constructed with any desired length (column 10, lines 47-50). Therefore, the bypass stent graft (56) is inherently capable of being positioned outside the vessel in a perivascular space and bent back towards the vessel in order to be positioned in a sealing relationship with the vessel such that the bypass stent graft (56) bypasses a portion of the vascular anatomy. In the alternative, it would have been obvious to bend the bypass stent graft (56) back towards the vessel to be positioned in a sealing relationship with the main vessel in order to bypass a portion of the vascular anatomy.

Regarding claim 3, Evans et al. disclose an access port (Figure 15, element 55) defined by an edge (inner ring portion of port 55 between the outer and inner surface of the stent graft 52) and comprising a seating surface (inner surface of stent graft 52 about the edge of port 55). Figure 16 shows the proximate end of the bypass stent graft

(56) comprises an engaging surface (outer surface of stent graft 56 that is inserted in port 55) such that when the bypass stent graft (56) is received in the access port (55), the seating surface and the engaging surface form a seal that inhibits blood flow. In the case where the bypass stent graft (56) is positioned outside the vessel in a perivascular space as described above, it is inherent that the seal established inhibits blood flow into the perivascular space.

Regarding claim 6, Evans et al. disclose at least the proximate end of the bypass stent graft (56) comprises a shaped memory alloy (column 2, lines 24-29), and Figure 16 shows the sealing relationship between the engaging surface and the seating surface after activation.

Regarding claim 7, Figure 16 shows the proximate end (portion inserted in access port 55) of the bypass stent graft (56) resides in a first vessel (1L1) and the distal end of the bypass stent graft resides in a second vessel (1L2).

6. Claims 10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (Patent No. 5,653,743).

Regarding claim 10, Figure 1 shows a main vessel stent graft (1) capable of providing a flow path through an aneurysm of a vessel. Figure 1 shows at least one access port (7) that is inherently capable of being aligned with a corresponding number of branch vessels in the aneurysm, since all one would have to do is rotate and/or move the stent graft (1) in a particular direction until the port (7) is aligned with the branch vessel. Martin further discloses at least one branch connecting stent graft (8) received in a corresponding one of the at least one access port (7) on a wall of the main vessel

stent graft (1) forming a sealing relationship. Furthermore, the distal end of the branch connecting stent graft (8) is inherently capable of residing in a branch vessel, forming a sealing relationship, and the branch connecting stent graft is inherently capable of providing a flow path through an aneurysm.

Regarding claim 12, Figure 1 shows an access port (7) defined by an edge (9), and a seating surface (inner portion about edge 9 that is located between the outer and inner surface of the main vessel stent graft 1). The proximate end of the branch connecting stent graft (8) comprises an engaging surface (the outside surface of the proximate end), and Figure 1 shows a sealing relationship between the engaging surface of the branch connecting stent graft (8) and the access port (7).

Regarding claim 13, Figure 5 shows that at least one branch connecting stent graft (8) comprises a plurality of branch connecting stent grafts.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Shmulewitz (Patent No. 5,961,548).

Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose puncturing the wall of the main vessel stent graft to establish the access port (55). Shmulewitz teaches puncturing the wall of the main vessel stent graft (perforations; Figure 3A, element 31) in order to join a second section in a separate step of the implantation process (column 2, lines 26-29). This method enhances the ease with which the legs of the graft may be deployed in the branches of a bifurcated body lumen (column 2, lines 13-16). It is obvious the punctures would have to be expanded in a controlled pattern in order to provide an access port for the bypass stent graft. Therefore, to puncture the wall of the main vessel stent graft of Evans et al. and expand the puncture in a controlled pattern would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ease the process of deploying the stent grafts.

9. Claims 4, 5, 9, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Venbrux (Patent No. 5,443,497).

Regarding claims 4 and 5, Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose a material between the seating surface and the engaging surface. Venbrux teaches any adhesive material can be used (column 3, lines 51-53) between a seating surface (underside of flared ends 36 and 38) and an engaging surface (outside of tubular members 20 and 28) in order to ensure a robust connection.

Therefore, to construct the bypass stent graft of Evans et al. with any adhesive material between the seating and engaging surface would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a durable connection between the bypass stent graft and the main vessel stent graft.

Regarding claim 9, Evans et al. do not teach the proximate end of the bypass stent graft is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the proximate end of the bypass stent graft of Evans et al. flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts.

It is noted that applicant is invoking 112 6th paragraph. Regarding claims 19 and 20, Evans et al. disclose a vascular stent graft comprising a first stent graft (Figure 1, element 52) with a port (55) in a wall inherently capable of aligning with a wall of a vessel (see above rejection), and a second stent graft (Figure 16, element 56) being received in the port (55) in the wall inherently capable of extending into a perivascular space (see above rejection). Evans et al. do not disclose the means for coupling the first stent graft and the second stent graft in a sealing relationship about the port. Venbrux teaches any adhesive material can be used (column 3, lines 51-53) between a seating surface (underside of flared ends 36 and 38) and an engaging surface (outside of tubular members 20 and 28) in order to ensure a robust connection. Therefore, to construct the vascular stent graft of Evans et al. with a means for coupling the first stent

graft and the second stent graft in a sealing relationship to inhibit blood flow would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a durable connection between the first stent graft and second stent graft. Furthermore, it is obvious in the case where the bypass stent graft (56) is extended in a perivascular space as described above, the sealing relationship inhibits blood flow into the perivascular space.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Martin.

Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose a branch connecting stent. Martin teaches a branch connecting stent graft (Figure 1, element 8) coupling a main vessel stent graft (Figure 5, element 1) and a bypass stent graft (18), so that other arteries and vessels are not covered or bypassed (column 1, lines 23-33) during stenting. Figure 5 shows the branch connecting stent graft (8) couples the main vessel stent graft (1) and the bypass stent graft (18) in a sealing relationship. Therefore, to construct the vascular stent graft of Evans et al. with a branch connecting stent graft would have been obvious to one of ordinary skill in the art at the time the invention was made in order to maintain blood flow through all arteries and vessels when stenting a system.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Shmulewitz.

Martin discloses a vascular stent graft as described in claim 10, but does not

disclose puncturing the wall of the main vessel stent graft to establish an access port. Shmulewitz teaches puncturing the wall of the main vessel stent graft (perforations; Figure 3A, element 31) in order to join a second section in a separate step of the implantation process (column 2, lines 26-29). This method enhances the ease with which the legs of the graft may be deployed in the branches of a bifurcated body lumen (column 2, lines 13-16). It is obvious the punctures would have to be expanded in a controlled pattern in order to provide an access port for the bypass stent graft. Therefore, to puncture the wall of the main vessel stent graft of Martin and expand the puncture in a controlled pattern would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ease the process of deploying the stent grafts.

12. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Dereume et al. (Patent No. 5,639,278).

Regarding claim 14, Martin discloses a vascular stent graft as described in claim 10, but does not disclose that it is expandable. Dereume et al. disclose a stent graft comprising an expandable material (column 1, lines 18-26), so that it is of a size and shape suitable for insertion into the desired body passageway (column 2, lines 61-64) when unexpanded. Figure 22 shows the sealing relationship once the graft is expanded. Therefore, to construct at least the proximate end of the branch connecting stent graft of Martin with an expandable material would have been obvious to one of ordinary skill in the art at the time the invention was made in order to insert the branch connecting stent graft into the desired passageway.

Regarding claim 16, Martin discloses a main vessel stent graft (Figure 1, element 1), inherently capable of residing in a main vessel, and at least one branch connecting stent graft (8). Figure 4 shows the at least one branch stent graft (8) comprises a distal end (not labeled) and a proximate end (not labeled); the proximate end resides about a wall of the main vessel stent graft (1). It would have been obvious to include at least one radiopaque marker on the proximate end of the branch connecting stent graft (8) such as the ones on the main stent graft (platinum wire; Figure 1, elements 12 and 11) in order to allow its location to be tracked (column 3, lines 8-21). A wall of the main vessel stent graft is designed to form an access port (7) for each branch connecting stent graft (8) such that each of the access ports (7) are aligned with the proximate end; the alignment being identifiable by the at least one radiopaque marker (column 3, lines 8-21). Martin does not disclose a corresponding number of connecting stents. Dereume et al. teach connecting stents (Figure 26, element 121) in order to provide a branched device for use in the treatment and/or repair at branched vessel locations (column 3, lines 42-45). Figure 27 shows each of the connecting stents have a main vessel seating surface (125) and a branch vessel seating surface (124), such that the main vessel seating surface engages the wall of the main vessel stent graft (113) in a sealing relationship and the branch vessel seating surface engages a wall of the branch stent graft (109) in a sealing relationship (Figure 26). Therefore, to construct the vascular stent graft of Martin with connecting stents would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide treatment and/or repair at branched vessel locations.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Venbrux.

Martin discloses a vascular stent graft as described in claim 10, but does not disclose the proximate end of the branch connecting stent graft is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the proximate end of the branch connecting stent graft of Martin flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts.

14. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Dereume as applied to claim 16 above, and further in view of Venbrux.

Regarding claim 17, Martin in view of Dereume disclose a vascular graft stent as described in claim 16, but does not disclose that the main vessel seating surface of the connecting stent is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the seating surface of the connecting stent of Martin in view of Dereume flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts. Regarding claim 18, Martin does not disclose that the branch vessel seating surface is expandable.

Dereume teaches the branch vessel seating surface is expandable (column 1, lines 18-26) so that it is of a size and shape suitable for insertion into the desired body passageway (column 2, lines 61-64) in its unexpanded state. Figure 22 shows that the branch vessel seating surface (not labeled) is flush with the wall of the branch stent graft(109). Therefore, to construct the branch vessel seating surface of Martin to be expandable would have been obvious to one of ordinary skill in the art at the time the invention was made in order to insert the branch connecting stent graft into the desired passageway.

Response to Arguments

15. Applicant's arguments filed 02 August 2006 have been fully considered but they are not persuasive. Applicant argues primarily that the amended claims contain new limitations that are no longer disclosed or taught by the prior art. Although the prior art is not intended to reside in a perivascular space (thereby inhibiting blood flow into the perivascular space), align with a puncture point on a wall of a vessel, reside in aneurysms, and reside in branch vessels, the prior art is capable of performing these functions since it meets the structural criteria as set forth by the metes and bounds of the claimed limitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Marsham*, 2 USPQ2d 1647 (1987).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
September 8, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/12/06.